Analysis of 7-Year Physician-Reported Adverse Events in Esophagogastroduodenoscopy

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Introduction: The number of negligence claims against physicians and health institutes is increasing and has become a serious financial problem. Reporting adverse events became a mandatory behavior for quality assurance purposes and for preparing potential claims.

Aim: To evaluate endoscopists' reports on adverse events in esophagogastroduodenoscopy (EGD).

Methods: We analyzed all the reports of gastroenterologists on EGD adverse events to the risk management authority, between January 1, 2000, and December 31, 2006. Clinical and epidemiological details about the patients, procedures, and adverse events were computed, discussed, and evaluated.

Results: Thirty-nine cases of EGD adverse events were reported. There were 15 cases (38.5%) of men, and the average age was 58.1 ± 21.6 years. In this period, 314,803 EGDs were performed by the institutes concerned, and the number of adverse events was 0.5 to 2.3 for 10,000 EGDs per year. Perforation occurred in 1 of 31,480 procedures, bleeding in 1 of 39,350 procedures, and respiratory complications in 1 of 157,401 procedures. Trauma to teeth happened in 1:31,480 procedures.

Conclusions: This is the first study in Israel about physicians' reports of EGD adverse events. Reporting adverse events in EGD should be encouraged for improving patients' safety.

Key Words: esophagogastroduodenoscopy, defensive medicine, perforation, bleeding, sedation

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More than 60% of the Israeli population has health insurance at Clalit Health Services (CHS). The physicians of CHS, in the community as well as in hospitals, have professional insurance at the same company. The number of negligence claims against physicians and health institutes is increasing continuously in Israel, as in the rest of the Western world, and has become a serious financial burden. Health economics became critically unstable, and a risk management strategy for decreasing claims and reducing damages becomes an integral part of every health plan in Israel. It was reported recently that 93% and 98% of American and Japanese physicians, respectively, practice defensive medicine, such as assurance behavior and avoidance behavior.[1,2]

Health organizations in Israel require immediate reporting of any mistake or complication in patients' management. Such reporting provides an opportunity to prepare an adequate legal defense to potential claims and to discuss the case when a personal or system failure is suspected. Sometimes, physicians are reluctant to report mistakes, facing a self-imaging or ego conflict. Aggressive persuasive efforts of health organizations, claiming that early reports are for the physician's own benefit, gradually overcome this problem, and regular reporting increasingly approach the rate of real-life events. Still, underestimation of medical complications exists.

In this study, we analyzed the reports of CHS gastroenterologists on EGD adverse events to the risk management authority, between January 1, 2000, and December 31, 2006. From the physicians' reports, we intended to study the pattern of adverse events in EGD in Israel and to estimate their incidence and outcome.

METHODS

All the reports of physicians associated with EGD adverse events or complications of health institutes covered by Madanes Insurance Group, between January 1, 2000, and December 31, 2006, were summarized by the authors during several meetings. Clinical and epidemiological details about the patients, procedure, and adverse event were computed into an excel sheet, discussed, and evaluated by all 5 researchers. Date, time of the day, and place of the EGD, background diseases and operations, medications, indication, additional procedure such as dilatation, biopsy and polypectomy, completeness of informed consent, treatment with anticoagulant or antiplatelet adhesion agent, adverse events and the time of diagnosis, and treatment of complication and outcome were all thoroughly discussed and computed. The number of EGDs performed for the members of CHS in Israel, between 2000 and 2006, was extracted from CHS data base, for each year of the study. The incidence of EGD adverse events was separately calculated for members of CHS, according to the data base for this period. The incidence of adverse events was calculated for each year according to the physicians' reports (annual reports, numerator) and the number of EGDs performed every particular year (enumerator).

A Quantum (Q) value, a parameter for a potential claim and its worth in Israeli Shekels, was calculated for each case, and assign Q = 0 (no potential claim) or Q > 0 (potential claim). Parameters that build the Q are as follows: severity of complication, pain, suffering, decrease in the ability to work and have salary (in relationship to income and family status), need of help for daily activity, potential changes in housing or relocation, life expectancy, expenses in the particular case, and experience with similar cases in the past.

The statistical analysis was performed using SPSS version 13 and MINITAB version 15.2. The results are expressed as mean ± standard deviation, and $P < 0.05$ is considered

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TABLE 1. Demographic and Clinical Data of the Reported Cases, N = 39 (100%)

Parameter	n	%
Sex		
Men	15	38.5
Women	24	61.5
Age		
Average ± SD (y)	58.1 ± 21.6	
Median (y)	67	
Range (y)	20–80	
>65 y	21	53.8
Referral center		
Hospital	25	64.1
Community unit	14	35.9
Indication for EGD		
Dyspepsia	25	64.1
Iron deficiency anemia	4	10.3
Esophageal disease	7	17.9
Other	3	7.7
State of urgency		
Elective	24	61.5
Urgent	15	38.5
Procedure characteristics		
Diagnostic (with or without biopsy)	38	97.5
Removal of foreign body	1	2.5
Record of 2 or more chronic diseases	9	23.1
Record of 2 or more operations	17	43.6
Record of 2 or more medications	10	25.6
Anticoagulant or antiplatelet therapy		
None	22	56.4
Aspirin	7	17.9
Unknown	10	25.7

significant. Kaplan-Meier curves and Logrank and Wilcox nonparametric tests were used to determine difference in age distributions by outcome, anticoagulant treatment, time to detect, and urgency of procedure.

RESULTS

Thirty-nine cases of EGD adverse events were reported to Madanes Insurance Group between January 1, 2000, and December 31, 2006, 34 cases of them (87.1%) belong to CHS.

TABLE 2. Distribution of 39 EGD Adverse Events Along 7-Year Period for CHS Members

Year	Number of Adverse Events	Number of EGDs Performed	Number of Adverse Events Per 10,000 Procedures
2000	2	32,359	0.6
2001	2	38,936	0.5
2002	10	43,668	2.3
2003	6	46,838	1.3
2004	6	47,645	1.3
2005	5	51,289	1.0
2006	3	54,068	0.6
Total	34	314,803	1.1

TABLE 3. Adverse Events in EGDs, N = 39 (100%)

Parameter	n	%
Complication		
Perforation	10	25.6
Bleeding	8	20.5
Teeth trauma	10	25.7
Cardiovascular and respiratory event	2	5.2
Other	9	23.0
Time detected		
Immediately	27	69.2
Within 24 h	9	23.1
More than 24 h	2	5.1
Unknown	1	2.6
Treatment		
Operation	10	25.6
Hospitalization and conservative treatment	12	30.8
Ambulatory treatment	15	38.4
Unknown	2	5.2
Outcome		
Residual damage	8	20.5
Complete healing	22	56.4
Death	4	10.3
Other	4	10.3
Unknown	1	2.5

Clinical and demographic data of the cases are given in Table 1. There were 15 cases of men (38.5%), and the average age was 58.1 ± 21.6 years, with range of 20 to 80 years and median of 67 years. Twenty-one patients (53.8%) were 65 years or older. Thirty events (76.9%) were reported voluntarily by the staff (primary report), and 9 (23.1%) were reported after a claim (secondary report). Most of the procedures were for diagnostic reasons and performed on an elective basis. Nine cases (23.1%) had 2 or more chronic background diseases, 17 cases (43.6%) have undergone 2 or more operations, and 10 patients (25.6%) were regularly treated with 2 or more medications, including aspirin (17.9%).

Distribution of 39 EGD adverse events along 7-year period for CHS members is demonstrated in Table 2. In this period of time, 314,803 EGDs were performed by the institutes concerned. The number of adverse events was between 0.5 and 2.3 for 10,000 EGDs. In 2002, this ratio was significantly higher, a finding that should be further investigated. Perforation occurred in 1 of 31,480 procedures, bleeding in 1 of 39,350 procedures, and respiratory complications in 1 of 157,401 procedures. Trauma to teeth happened in 1 of 31,480 procedures.

Distribution of the procedures along the week working days: lower in Sunday and Friday and higher in Monday, Tuesday, and Wednesday, 5.1% minimum and 28.2% maximum. Twenty-five events (64.1%) happened in the morning and 8 (20.5%) in the afternoon. Informed consent was properly filled

TABLE 4. Claims and Legal Status for July 16, 2010

Parameter	n	%
Compromise agreement	7	18.0
Limitation	6	15.4
Ongoing claim	1	2.6
Other	25	64.0

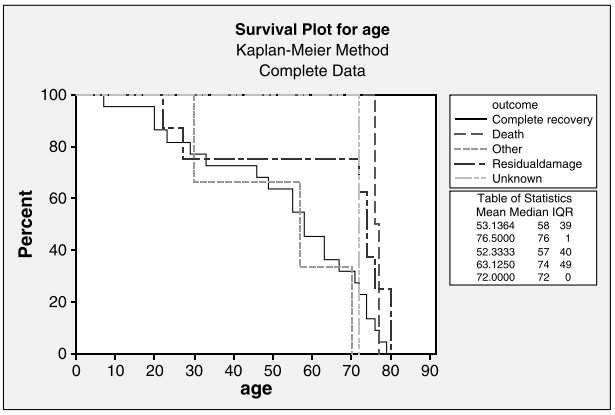

FIGURE 1. Survival plot for age by outcome.

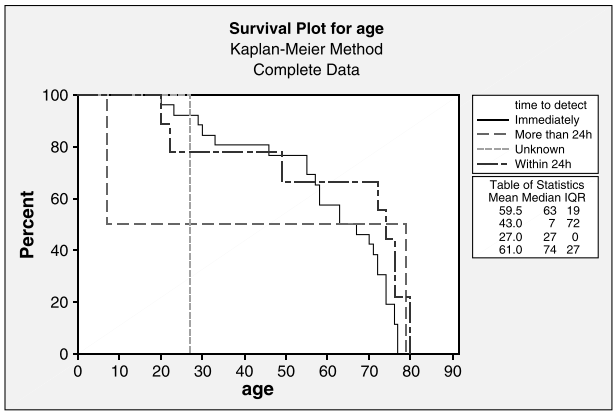

FIGURE 3. Survival plot for age by time to detect the adverse event.

and signed in 24 cases (61.5%) and partially filled in 3 additional cases (7.7%). The informed consent form could not be found in the patients' files in 12 cases (30.8%).

Description of adverse events and clinical outcome is demonstrated in Table 3. There were 10 perforations, 25.6% of the adverse events. Most of the cases were detected and reported immediately or within 24 hours. Ten patients were operated upon (25.6%), and 22 patients required hospitalization. There were 4 mortality cases, and 8 patients had residual damage.

The status of legal claims is presented in Table 4. Only minority of the cases came to court, 7 achieved compromise agreements, and 1 is engaged in ongoing negotiations.

The Q value was zero in 20 cases (51.3%) and 10,000 or higher in 13 cases (33.3%), with mean of 22605 ± 80313, median of 1664, and range of 0 to 500,000.

Age distribution by outcome showed significant differences ($P < 0.05$) with a median age of full recovery of 58 years (mean, 53), a death median age of 76 years (mean, 76), and a median age for residual damage of 74 years (mean, 63) (Fig. 1).

Figures 2 to 4 present survival curves of age by anticoagulant, time of detection, and urgency of the procedure and indicate no statistically significant differences.

Tracking of the number of adverse events, by year, with a control chart shows stability in the number of events with an average of 5.57 events per year (Table 2 and Fig. 5).

DISCUSSION

Reporting adverse events and complications is part of daily routine work in Israeli medicine, encouraged by the health organizations and the insurance companies but not supported by objective measures.[3] With sensational mass media reporting on medical malpractice, physicians have begun to focus on risk management activities, leading them to practice defensive medicine. This strategy enables preparation for potential claims, collecting specific data, and assigning dedicated sum of money by the insurance company and also collects data for the purpose of quality assurance measurements.

Described adverse events and complications of EGD included perforation, bleeding, sedation-associated cardiovascular and respiratory problems, teeth damage, and missing lesions or misinterpreting them.[4]

The manner in which the incident is handled has important consequences for the affected patients' decision to take legal action.[5,6] Complete disclosure of adverse event or near-miss situations to the patients and family members may prevent lawsuits, but this strategy is not always practiced because of shame, embarrassment, fear of losing trust, and lack of training.[7–9]

In the present paper, we described 39 cases of adverse events during EGD reported to the Madanes Insurance Group in 7 years. Not surprisingly, most of the cases were of elderly patients with a background of chronic diseases. The rate of perforation and bleeding are very low, and the rarity of respiratory and cardiovascular complication, most probably because of sedation, is outstanding. Only 2 cases were reported; thus, a ratio of 1 to 157,401 procedures could be calculated. The clinical outcome was not so favorable. There were 4 cases of mortality

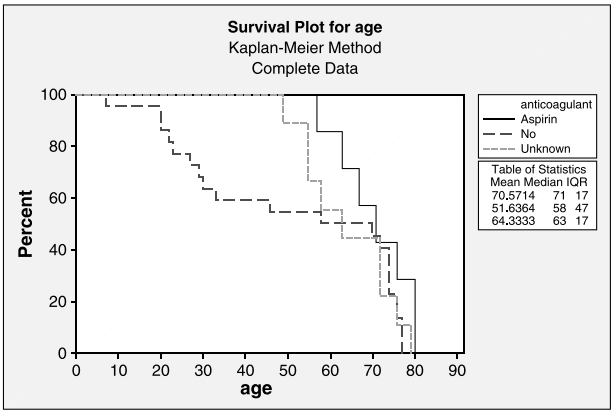

FIGURE 2. Survival plot for age by anticoagulant treatment.

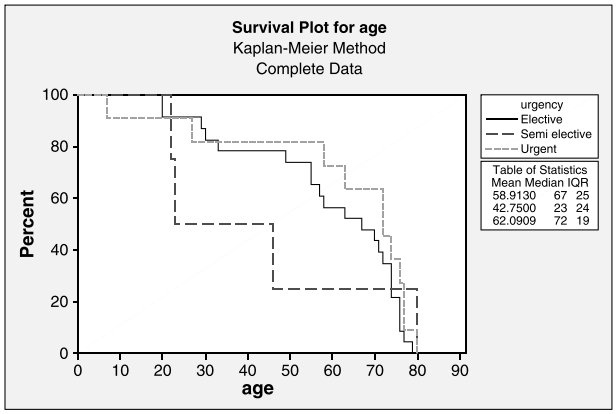

FIGURE 4. Survival plot for age by urgency of the procedure.

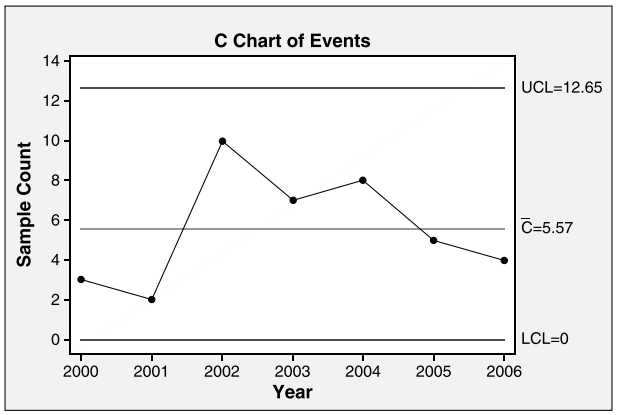

FIGURE 5. Control chart of number of EGD adverse events per year.

(10.3%), 10 patients underwent operation, and 8 patients were left with residual damage.

Most of the complications were diagnosed early, 69.2% immediately after the procedure, and additional 23.1% within 24 hours. In 20 cases, the Q value was zero, and no further legal evaluation should be performed, whereas in 13 cases, the Q value was 10,000 and higher, and these cases were evaluated thoroughly for potential litigations and financial compensation. Most of the adverse events were reported from hospitals, although the numbers of EGDs are very similar between community units and hospitals. This finding may be explained by the more serious cases that undergo EGD in the hospital than in the community units. Because we could not find any similar study about gastroenterologists' EGD adverse events reports, this finding should be confirmed and carefully further investigated.

It is not possible to estimate the true rate of adverse events according to these voluntary reports. We believe that there are far more cases than reported. Milch and colleagues[10] analyzed 92,547 reports from 26 acute care hospitals and found a wide reporting rate difference across hospitals, 9 to 95 reports per 1000 inpatient days (median, 35). Thus, reporting should be improved. Vincent and coauthors[11] described 4 main reasons for litigation: concern with standard of care, the need for explanation, compensation, and accountability. Reporting adverse events is an essential component in preparation of staff and organization that should have to account for their actions. In a survey of teaching hospitals, Kaldjian and colleagues[12] demonstrated that most faculty and resident physicians are inclined to report harm-causing hypothetical errors, but only a minority has actually reported an error.

Kern[13] investigated 99 malpractice cases tried in the United States, federal and state civil court system, involving 103 allegations of negligence over a 21-year period. There were 44 cases of misdiagnosis, 25 cases of iatrogenic injury, and 16 cases of medical complication. In 8 cases (8%), lack of informed consent was the reason for litigation. This series is different from our cohort, where misdiagnosis was not a part of it.

Our study is limited by being retrospective and lack of essential data from the patients' files and source documents. We cannot compare statistically the rate of adverse events in the morning and afternoon shifts because we have no data on the global EGDs amount performed in these shifts separately. In addition, the follow-up is too short to evaluate the legal outcome of this cohort. We do not have information about 25 of 39 patients that still can sue or complain.

In conclusion, this is the first study in Israel about physicians' reports of EGD adverse events. We believe that looking at these reports is helpful in analyzing safety factors in EGD. Perforation, bleeding, teeth trauma, cardiovascular, and respiratory events should be avoided by a carefully handled procedure. Adverse event should be ruled out at the end of every procedure; thus, early detection and proper therapy will improve survival and prevent mortality or residual damage. In our series, there were 4 (10.3%) cases of mortality, and early detection was described in only 69.2% of the cases. Encouraging reports about adverse events in EGDs will improve patient safety. Knowing the incidence of adverse events and their outcome will help providers achieve better outcome when such complication occur.

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